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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,161	04/26/2001	Hidetaka Iwai	206580US0	6889
22850	7590	06/05/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			YU, GINA C	
			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 06/05/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/842,161	Applicant(s) IWAI ET AL.	
	Examiner Gina C. Yu	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 17, 2005 has been entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 6-8, 11-21, 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu (JP 63-126542).

Yu teaches transparent microemulsions containing hydrophilic ionic surfactants and oil components used for pharmaceuticals and cosmetics. See English Translation, p. 2, lines 1 –17; p. 7, lines, 9-10. The reference teaches that the ratio of the nonionic surfactant to the oil ingredients in the invention may range from 1:05 to 1:10, and the emulsified particle size is 0.01-0.1 microns. See instant claims 1 and 3. See p. 4, lines 11-12. The application of the invention, such as liquid detergent, shampoo, hair tonic, etc, are disclosed in p. 7, lines 19-24. See instant claims 18 and 19.

The reference teaches anionic surfactants, cationic, amphiphilic surfactants, or mixture of thereof in p. 4, line 12 – p. 5, line 5. See instant claims 11-13. The reference

teaches N-acylglutamic acid salts and specifically teaches monosodium N-lauroyl glutamate, disodium N-stearoyl glutamate, monosodium N-myristearyl-L-glutamate.

See p. 4, fifth paragraph; instant claims 27.

While N-stearoyl-N-methyltaurine sodium salt (C18) is not specifically taught, the limitation is viewed obvious because the reference teaches N-myristoyl-N-methyltaurine sodium salt (C14). See p. 4, 4th par; instant claims 29-30. Examiner views that a skilled artisan would have had a motivation to substitute one higher fatty acid amide sulfonic acid salt for the other in expectation of successfully producing a similarly stable microemulsion.

Since While the Yu reference does not teach dynamic surface tension of these surfactants, examiner notes that, since the prior art surfactants are the same compounds used in applicants' invention, and these prior art surfactants also have the dynamic surface tension that meets the recited requirement. For claim 31, the recited surfactants are disclosed in Example 31 and p. 4, 4th-5th par.

Although Yu does not disclose any specific example formulation having the ratio of oil to hydrophilic surfactants that is "more than 11.67", the ratio of 10:1 is taught by the reference. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The Yu reference teaches making a stable and

transparent microemulsion with the nonionic surfactants recited by applicants and the oil: nonionic surfactant that is close to the applicants' range. Also taught are the various organic and silicone oils that can be used alone or mixed in the oil phase, in an amount up to 60 % wt. Given these conditions, a skilled artisan would have found an optimal ratio between oil and hydrophilic surfactant ratio by routine experimentations.

As for claims 1, 6, 7, and 15, the process limitations are obvious in view of the Yu reference teaching, in p. 7, lines 4- 8, to use a high pressure homogenizer or ultrasound emulsifying machine to produce strong shear stress of 400 atm or higher, or preferably of 600 atm or higher at a temperature below 50 °C. See instant claim 20. Examiner takes the position that employing the prior art equipments would obviously produce the shearing rate of the instant claims, unless proven otherwise.

Claims 4, 5, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-31 above, and further in view of Drapier et al. (US 6121228) ("Drapier").

Yu further teaches that while liquid oils are preferred, oils in solid state may be used if they become liquid when mixed, suggesting mixing liquid and solid fatty components. See p. 5, line 6 – p. 6, last line. See also Tables for high alcohols, such as isostearyl alcohol, showing satisfactory transparent microemulsions. The Yu reference fails to teach an example of composition having both solid and liquid oil with specific viscosity.

Drapier teaches water-in-oil microemulsion liquid detergent having viscosity ranging from 6-300 milliPascal. See col. 4, lines 47 – 67; col.14, lines 17 - 26.

Given the teaching in Yu that the both liquid and solid oils may be used for variety of microemulsion applications such as liquid detergents, and the teaching that thickening agents may be added in the compositions, it would have been obvious to one having ordinary skill in the art to have expected successfully producing a product having desired viscosity by routine experimentations. The routineer who contemplates to formulate the liquid detergent according to Yu would have been motivated to adjust the viscosity as taught by Drapier.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 11-21, 27- 31 above, and further in view of Ansel (Pharmaceutical Dosage Forms and Drug Delivery Systems, 1990 5th ed.).

While Yu teaches that the HLB of the ionic surfactants should be hydrophilic since it is necessary to obtain oil-in-water type microemulsions, the reference fails to teach HLB of the surfactants.

Ansel teaches that surfactants having HLB of 8-18, and particularly HLB of 15-18 produce transparent microemulsion compositions. See Ansel, p. 244 col. 2, lines 9-13.

Given the general teaching of formulating o/w microemulsion compositions in Yu, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to look to the prior arts such as Ansel for specific types and characteristics of the emulsifiers conventionally used in microemulsions.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-31 above, and further in view of Gers-Barlag et al. (US 5876702) ("Gers-Barlag").

The Yu reference fails to teach the surface tension of the oil components.

Gers-Barlag teaches that o/w microemulsions are obtained from oil components having surface tension of less than 30 mN/m. See col. 17, lines 15 – 30. The reference teaches that oils having a polarity between 10-20 mN/m are preferred. See also col. 17, lines 31 – 46 for specific types of oils.

Given the general teaching of formulating o/w microemulsion compositions in Yu, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to look to the prior arts such as Gers-Barlag for specific types and characteristics of oils conventionally used in microemulsions.

Claims 23 and 25 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-31 above, and further in view of Diec et al. (US 6468551 B1) (“Diec”).

Yu, discussed above, fails to teach using silicone oil in the microemulsion. Diec teaches cosmetic o/w microemulsions comprising hydrophilic o/w emulsifiers. See Example 22, comprising oil and the emulsifier in the weight ratio of greater than 10:1. See also col. 45, lines 31-39. The reference teaches that silicone oils are “advantageously” used in the invention, particularly mentioning polydimethylsiloxanes. See col. 25, lines 43 – 53. See instant claim 23 and 25.

Given the general teaching of formulating o/w microemulsion compositions in Yu, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to look to the prior arts such as Diec for specific types oils conventionally used in microemulsions for cosmetic purposes. The skilled

artisan would have expected to successfully produce a cosmetically advantageous composition.

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-31 above, and further in view of Brunetta et al. (US 5562911) ("Brunetta").

Yu, discussed above, fails to teach fluoro-based oil.

Brunetta teaches that due to the formation of protective film on skin, the use of perfluoropolyether in cosmetic formulation is well known in the art. See col. 1, lines 15 – 56.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substitute the oil in the Yu formulation with perfluoropolyether as motivated by Brunetta, because of the expectation of successfully producing a o/w microemulsion which forms protective film on the skin.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-3, 6-8, 10-21, 27-31 above, and further in view of Shiojima et al. (US 6066316) ("Shiojima").

While the Yu reference teaches that nonionic surfactants are used to make microemulsions, the reference fails to teach polyoxyethylene alkyl ethers. See translation, p. 2, 3rd par.

Shiojima teaches a transparent oil-in-water hair cosmetic composition comprising POE behenyl ether. See col. 48, Test Example 22. The formula contains 32.5 % by

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weight of oil phase (Carnauba wax and liquid petrolatum) and 3.0 % of POE-10 behenyl ether, meeting the weight ratio requirement of instant claim 1.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the invention of Yu by substituting the hydrophilic surfactants with POE-10 behenyl ether as motivated Shiojima because of an expectation of successfully producing cosmetic compositions with similar effects or hair cosmetic emulsion compositions.

Oath/Declaration

The declaration filed on January 9, 2006 was fully considered but does not place the application in allowable condition.

The declaration compares Examples 28, 31, and 32 of the Yu reference with similar compositions having the ratio of oil:surfactant ratio of above 11.67 as required by the present invention. The surfactants used in the example formulation of the reference and the modified comparison samples of these examples are said to have a dynamic surface tension of above 57mN/m. The declaration indicates that a mere increase of the ratio of oily components to surfactant in the prior art compositions does not improve transparency of the emulsion.

Examiner takes the position that the data in the declaration does not amount to unexpected results. The result indicates that the high transparency is the function of the dynamic surface tension of the known nonionic surface active agent. The basis of the rejection is not that the modifying the oil:surfactant ratio would have resulted in better transparency and stability of the emulsion. The use of the specific surfactants that are

claimed by applicants to make microemulsions having high oil:surfactant weight ratio has been already known, according to Yu. Examiner views that discovery of the surfactants that yields better transparency among the prior art nonionic surfactants, as applicants have done in this case, is within the skill of the art.

Response to Arguments

Applicant's arguments with respect to claims 1, 2, and 4-31 have been considered but are unpersuasive, as indicated in the advisory action dated February 27, 2006.

Applicants assert that Yu fails to suggest making an emulsion having at least 11.67 parts oily component to surface active agent having a dynamic surface tension below 57 mN/m. As indicated in the rejection, the reference teaches using those surface active agents in oil:surfactant ration of 10:1 to make a transparent microemulsion for cosmetics. It is reiterated that differences in concentration in general will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this case, while applicants assert to have found a specific type of surface active agents provide "superior transparency and stability" in a particular oil:surfactant ratio, examiner views that the claim is obvious over the prior art because the reference teaches the surfactants and the oil:surfactant ratio that is close to the claimed ratio.

Applicants also assert that applicants have shown criticality of selecting a surface active agent having a dynamic surface tension value of 57mN/m for obtaining highly transparent and stable emulsion having high oil components. The argument is viewed unpersuasive as discussed above in Oath/Declaration.

Conclusion

No claims are allowed.

This is a continued examination of application under 37 CFR 1.114. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605.

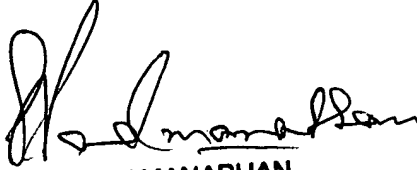
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The examiner can normally be reached on Monday through Friday, from 7:00AM until 4:30 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gina Yu
Patent Examiner



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER